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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,115	09/04/2001	Karl Miltner	BMID9817US	7059

27879 7590 06/11/2003

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EXAMINER

SEVER, ANDREW T

ART UNIT	PAPER NUMBER
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2851

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,115

Applicant(s)

MILTNER ET AL.

Examiner

Andrew T Sever

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,10,11,19 and 23-29 is/are rejected.
- 7) ☒ Claim(s) 2,6-18 and 20-22 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The specification lacks headings.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

2. Claims 6, 7, 12, and 13 are objected to because of the following informalities: There is no antecedent basis for "width X" or art recognized meaning for the term "X" in that context.

Appropriate correction is required.

For purposes of the prior rejection the "X" will be assumed to be the width of the detection zone as is taught in applicant's specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It could not be found where the specification teaches that the liquid either absorbs or does not absorbed the radiation.

Since it is a well known property of all materials (including fluids) that they partially absorb any radiation and partially reflect (hence while all materials have a speed of light through them that differs from that through vacuum), for purposes of a prior art rejection it will assumed that it is inherent that the sample liquid absorbs at least some of the radiation, while if the prior art teaches that radiation is transmitted through the liquid, it will be assumed that radiation is essentially not absorbed by the sample liquid. The

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applicant can overcome this rejection by pointing out the support for these claims in the specification as well as pointing out with respect to the claimed invention how these claims read over the prior art of record in the applicant's response.

Applicant should also note that if the examiner's assumptions are wrong about the liquid both absorbing radiation and essentially not absorbing it at the same time, then claim 28 should be amended to not be dependent on claim 27, since if the examiner's assumption is wrong the sample liquid can not then be both absolutely opaque and transparent at the same time to the same radiation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3-7, 10/1, 11/10, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Bolduan et al. (US 6,055,060)

The applied reference has a common assignee and one common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was

derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With regards to applicant's claims 1,5:

Bolduan et al. teaches in columns 8-10 with reference to figures 1 and 3-5 a method for the photometric analysis of test elements having a detection zone, the method being tolerant of positioning variations of the detection zone, comprising the steps of

- a. placing a test element (such as a capillary gap test element as is claimed by applicant's claim 5) in a holder such that the detection zone of the test element is positioned relative to an illumination unit having a first and a second light source, a positioning variation of the detection zone occurring in at least one direction (see figure 5),
- b. contacting the detection zone with a sample such that a detection system present in the detection zone leads to a photometrically detectable change in the detection zone when an analyte is present in the sample (see lines 3-30 of column 9, where Bolduan teaches that the detector evaluates if enough sample is present)
- c. activating the first light source to irradiate a first region of the detection zone, and detecting at least one of light reflected from the detection zone or light transmitted through the detection zone, in order to generate a first detection signal (see column 9 lines 3-8),
- d. activating the second light source to irradiate a second region of the detection zone which is displaced relative to the first region in the direction of the positioning

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variation and detecting at least one of light reflected from the detection zone or light transmitted through the detection zone in order to generate a second detection signal (see column 9 line 3-9),

e. comparing the first and the second detection signal and determining whether the first and/or the second detection signal has been obtained by illuminating an area situated completely on the detection zone and selecting the corresponding detection signal (see column 9 lines 9-30), and

f. determining the analyte concentration contained in the sample by analyzing the selected detection signal (inherent).

With regards to applicant's claim 3:

Bolduan et al. teaches in column 5 lines 47-67, the method of claim 1 further comprising

g. determining a first and a second base-line detection signal on an unused test element, and

h. standardizing the first and second detection signal by division by the corresponding base-line detection signal before determining the analyte concentration in step f.

With regards to applicant's claim 4:

Figure 1 shows that the first and second regions irradiated have essentially the same size.

With regards to applicant's claims 6 and 7:

As shown in figure 5, the first and second light source (L'1 and L''1) are aligned with the detection zone (A) and the Detector (D) such that first and second light source (L'1 and L''1) have their focal points located in a connecting line running essentially parallel to the width of the detection zone which inherently would be perpendicular to the capillary gap.

With regards to applicant's claims 10/1 and 11/10/1:

Figure 6A shows the irradiated regions overlapping on the test strip and in column 10 lines 26-39 Bolduan et al teaches the overlap is less than half the diameter of the irradiated regions.

With regards to applicant's claim 19

Bolduan et al. teaches in figure 1 and 5 a device for the photometric analysis of test elements comprising:

- an illumination unit with a first and a second light source (L1 and L2)
- a holder for holding a test element with a detection zone such that the detection zone is positioned relative to the illumination unit (see figure 5 which shows the test element's (T) detection zone's (A) position relative to the illumination unit (L1 and L2 as well as the detector D)

-a control unit (S) which activates the first light source during a first activation phase in order to illuminate a first region of the detection zone and activates the second light source during a second activation phase in order to illuminate a second region of the detection zone (see column 9 lines 1-30)

-a detection unit (D) with at least one detector (D) which detects light reflected from the detection zone or transmitted through the detection zone, the signal generated by the detection unit during the first activation phase being recorded as the first detection signal and the signal generated during the second activation phase being recorded as the second detection signal

-an analytical unit (E) which compares the first and second detection signal and determines whether the first and/or the second detection signal has been obtained by illuminating a region situated completely on the detection zone, and analyses a corresponding analyte detection signal in order to determine an analyte concentration in a sample.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markart (US 5,889,585.)

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Markart teaches in columns 3 and 4 a method for the photometric analysis of a test element with detection of sample application on a flat detection zone of the test element comprising the steps of irradiating a first (28) and second (26) detection zones, supplying sample liquid to a measuring field (14) of the test strip which is closer to the first measuring area (28) as is claimed by applicant's claim 26. Monitoring radiation transmitted through both measuring zones (inherently some of the radiation is absorbed by the sample liquid while essentially radiation is not absorbed by the sample since enough signal passes through to be detected as is believed claimed in applicant's claims 27 and 28). Detecting the presence of the sample liquid in the measuring zones from the change in the transmitted radiation. A signal is generated to alert the user to either supply additional liquid if necessarily, to stop supply liquid, or to start over if the test strip has been ruined. Once a proper amount of liquid is supplied the test apparatus determines the concentration of an analyte (blood sugar) in the sample liquid (blood). Markart does not however specifically teach a control zone, however one with ordinary skill in the art at the time of the invention would recognize that the second detection zone (26) could be used as the control zone as Markart describes in column 3 lines 50-67 that when insufficient blood is present the reflection from areas 26 and 28 differ and therefore less blood has reached the second detection zone and therefore the second zone serves the same function as a control zone as claimed by the applicant.

With regards to applicant's claims 24 and 25, Markart teaches the use of a test strip, it is well known in the blood testing arts that test strips frequently include capillary gaps, which generally run under the cover which would obviously be the detection zone,

so therefore the capillary gap runs below the detection zone as is claimed by applicant's claim 25. For example Thym et al. (US 6,036,919) teaches a capillary gap in column 6 lines 41-53.

With regards to applicant's claim 29, it is well known to those with ordinary skill in the blood testing arts that the results and error messages of the blood sugar measuring device are either outputted by an optical and/or acoustic signal.

Allowable Subject Matter

9. Claims 2, 8, 9, 10/8, 10/9, 11/10/8, 11/10/9, 12-18, 20-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter:

Claim 2 claims that the detection signal that has a lower intensity is selected, however, Bolduan's method averages the two signals. The prior art did not teach using this method either. Therefore claim 2 would be allowable if re-written in independent form including the subject matter of rejected claim 1.

Claims 8 and 9, claim that the regions irradiated are specifically oval or rectangular in shape, however neither Bolduan nor Markart specifically teach oval or rectangular shaped irradiation regions. Although figure 2 of Markart shows an oval shape region for first detection zone, the specification does not specifically teach that this region is oval shape, further Markart does not teach the method of applicant's claim 1 and no motivation besides hindsight would

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motivate one with ordinary skill in the art to use this teaching to modify Bolduan to use oval shaped irradiation regions. No prior art of record teaches rectangular regions. Claims 10/8, 10/9, 11/10/8, and 11/10/9 would also be allowable if the dependency of claim 10 were changed to remove the direct dependency on claim 1 and if claims 8 and 9 were re-written in independent form including the subject matter of their respective rejected base claims.

Claims 12 and 13 claim a specific relationship between the width of the two-irradiation regions and the width of detection area. This relation was not found in the prior art and therefore claims 12 and 13 would be allowable if re-written as independent claims including the subject matter of their rejected base claims 6 and 1 in the case of 12 and 12 in the case of 13.

Claim 14 claims that an additional light beyond the first two is present which irradiates a third region for detecting the presence of the sample. Bolduan teaches in column 9 lines 17-20 that an additional light source can be provided, however this light source to illuminate a smaller region and is to further refine the measurement in the evaluation zone evaluated by the other two light sources. No other prior art was found which could be combined with Bolduan to that taught using this third light for detecting the presence of the sample and therefore claim 14 would be allowable if written in independent form including the rejected base claim 1. Claims 15-18 are dependent on claim 14 and would be also allowable if claim 14 were re-written in independent form including its rejected base claim.

Claim 20 claims a third light which uses a second wavelength that is different from that of the first and second light sources, this was not found in the prior art in combination with a device as claimed in independent claim 19 which claim 20 is dependent on. Only devices with two light sources could be found. Although as has been previously stated Bolduan does teach

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the possibility of a third light, Bolduan makes no suggestion of using one with a different wavelength and there is no motivation to combine Bolduan with another prior art device to provide a third light source with a different wavelength. Therefore claim 20 would be allowable if written in independent form. Claims 21 and 22 are dependent on claim 20 and would also be allowable if claim 20 were re-written.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,103,197 to Werner

US 6,574,425 to Weiss et al.

US 4,755,058 to Shaffer

US 5,995,236 to Roth et al.

All teach photometric analysis devices with two light sources.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew T Sever whose telephone number is 703-305-4036. The examiner can normally be reached M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Adams can be reached at 703-308-2847. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9318 for regular communications and 703-872-9319 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.

AS

June 9, 2003


RUSSELL ADAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800